REMARKS

Claims 1-16 are pending before the Office.

Pursuant to 35 U.S.C. §§ 121 and 372, and in view of 37 C.F.R. § 1.499 and PCT Rules 13.1 and 13.2, the Office Action requires an election of a single invention to which the claims must be restricted.

The Office Action requires election of a single group selected from the following groups:

Group I, claims 1-8 and 11-16, drawn to a method of assessing the state of Alzheimer's disease;

Group II, claim 9, drawn to a kit comprising one or more polypeptide markers; and

Group III, claim 10, drawn to a kit comprising fragments of markers of a least 5 amino acids.

Applicants provisionally elect, with traverse, Group I, corresponding to claims 1-8 and 11-16. Applicants reserve the right to file divisional applications to any non-elected subject matter. Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks that follow.

The Office Action contends that the separate groups of inventions of Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. In particular, the Office Action alleges that the special technical feature linking the claims of Groups I-III are Alzheimer's disease-specific marker polypeptides which are alleged to be taught by Nitsch et al. (WO 00/25138) and thus, are not found to define a contribution over the art, as required by PCT Rule 13.2. Applicants respectfully disagree with the comments regarding Nitsch et al.; however, as the claims are not presently under rejection, Applicants will not provide a detailed response. Nevertheless, with regard to the requirement for restriction, Applicants respectfully submit that in view of the elected Group I, claims 1-8 and 11-16, and the elected species below, each of which pertain to Marker 1 (M1) of the present invention (i.e., marker 1, VGF4.8, SEQ ID NO: 17), the claims share a requisite special technical feature which defines a contribution over the art. Thus, the claims of Group I, II and III should be examined together in the same application.

Applicants respectfully point out that the M.P.E.P. in Section 1850(II) states that "an international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept. With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art."

The restriction requirement is not deemed proper because each of the claims of Groups I through III are linked so as to form a single general inventive concept; namely, methods and kits for assessing the state of Alzheimer's disease based on the detection of more or more polypeptide markers. Since the Groups of the invention are linked by the above "special technical features" as required under PCT Rule 13.2, a restriction should not be proper.

In addition, the Office Action requires election of various species of the invention, which are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species from which an election is required are:

(A) All molecular masses as listed in claims 1 and 9;

(B) All sequence identifiers as listed in claim 3;

(C) The species of polypeptides of claim 4, which are human cystatin C, Human beta-2 microglobulin, human myoglobin, neurosecretory protein VGF, a fragment of at least 5 amino acids of human cystatin C, a fragment of at least 5 amino acids of human beta-2-microglobulin, a fragment of at least 5 amino acids of human myoglobin, and a fragment of at least 5 amino acids of neurosecretory protein VGF; and

(D) The species of polypeptide fragments of claim 10, which are a fragment of at least 5 amino acids of human cystatin C, a fragment of at least 5 amino acids of human beta-2-microglobulin, a fragment of at least 5 amino acids of human myoglobin, and a fragment of at least 5 amino acids of neurosecretory protein VGF.

Applicants provisionally elect, with traverse, (A) molecular mass 4824 +/- 20 Da (Marker 1) of claim 1, (B) SEQ ID NO: 17 (Marker 1) of claim 3, (C) neurosecretory protein VGF (Marker 1), and (D) a fragment of at least 5 amino acids of neurosecretory protein VGF. Applicants reserve the right to file divisional applications to any non-elected subject matter. Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks that follow.

The species requirements are not deemed proper because each of the claims of Groups I through III are linked so as to form a single general inventive concept; namely, methods and kits for assessing the state of Alzheimer's disease based on the detection of one or more polypeptide markers that are indicative of Alzheimer's disease. Since the claims of the invention are linked by the above "special technical features" as required under PCT Rule 13.2, the election of species should not be proper.

Enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as prejudice to Applicants. Restriction has not been shown to be proper, especially since the requisite showing of a lack of unity of invention has not been made. Indeed, the search and examination of each species would likely be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner.

Consequently, reconsideration and withdrawal of the requirement for restriction are respectfully requested.

CONCLUSION

In view of the amendments and remarks made herein, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are respectfully requested. Please charge any required fee or credit any overpayment to Deposit Account No. 04-1105, reference number LeA36293[83672(303989)].

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Respectfully submitted,

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